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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,199	12/21/2001	Claudio De Simone	2818-72	4379
23117	7590	11/30/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/024,199		DE SIMONE, CLAUDIO	
	Examiner		Art Unit	
	Deborah K. Ware		1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 23-41 are presented for reconsideration on the merits.

Papers

The amendment filed August 17, 2004, has been received and entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Ved. Vesely et al. (US Patent No. 6,277,370) cited of record, note page 3 of Office action of May 19, 2004.

Claims have been newly amended to include *Lactobacillus brevis* strain DSM 11988.

The cited '370 patent does indeed teach *Lactobacillus brevis*, although a different strain thereof, ATCC 14869. Note column 7, lines 57-58.

Applicant's arguments filed August 17, 2004, have been fully considered but they are not persuasive. The argument that the cited '370 patent does not teach the DSM 11988 strain is noted, however, the reference does teach the usefulness of a strain of *Lactobacillus brevis*. It is well within the purview of an ordinary artisan to obtain a strain of *Lactobacillus brevis* which can use arginine. Further, the argument that *L. casei* of the instantly filed claims produces hydrogen peroxide and the *L. casei* of the cited prior art is noted; however, the claims are not limited to *L. casei* and the cited reference teaches that *L. salivarius* produces hydrogen peroxide of which in the instant claims the

choice of component a may be exclusively *L. salivarius* that produces hydrogen peroxide.

In addition, *L. gasseri* is not the only choice for component b and as evidenced by example 3 of the cited prior art the effective combination of non-producing and producing hydrogen peroxide strains of Lactobacilli for method of treating vaginitis is well known and taught by the cited prior art. Also note the abstract of the cited prior art. One of skill would have expected successful results for the treatment of infectious vaginitis using composition comprising lactobacilli having these particular properties as claimed herein. The particular combination of *Lactobacillus salivarius* and *Lactobacillus brevis* strains is taught by the cited prior art. Thus, the argument that various possible combinations of groups a) and b) are not disclosed is not deemed persuasive.

Further, albeit the strain DSM 11988 is not disclosed by the cited prior art, but one of skill would have been motivated to select for different strain having similar properties thereof in order to provide for the combination as claimed. Clearly one of skill in the art would have expected successful results because the combination is taught by the reference wherein the only difference is that the strain is different but the selective property of the disclosed strain is not different. One of skill in the art would be able to appreciate that the disclosed strain has the desired property and to select for another having this property is clearly an obvious modification of the cited prior art. Therefore, the claims are rendered obvious over the cited reference and are rejected over this reference under 35 USC 103 in light of the newly added amendment to claim 38.

Claims 23-41 remain also rejected under 35 U.S.C. 103(a) as being unpatentable over the Vesely et al patent discussed above in view of U.S. Patent 6,159,724 (Ehret), note specifically column 8, lines 61-62, for reasons of record.

Applicant's arguments filed August 17, 2004, have been fully considered but they are not persuasive. The argument that Applicant's description at pages 7-9 shows combining two hydrogen peroxide producing lactic acid bacteria does not increase the activity is not convincing since there was no description to support that such a combination would not; for example, there was no comparison in the description of the two: hydrogen peroxide producers, with arginine using and producer. The description only showed the one with arginine using and producer combination. Thus, the examiner fails to see how the description referred to by Applicant shows that such increase in activity would not be intrinsic.

Further, the argument that Ehret does not have an exact passage saying that an arginine-iminase utilizing lactic acid bacterium will increase the activity of hydrogen peroxide lactic acid bacterium is noted; however, the examiner directs Applicant to column 8, lines 61-62 wherein Ehret shows a arginine using strain of *Lactobacillus brevis* (strain DSM 9209). This strain is clearly shown to be using arginine to provide for a positive reaction for obtaining ammonia out of arginine. Thus, this strain of *L. brevis* is an arginine using strain as claimed, as most of the strains of *L. brevis* are arginine using strains. Thus, the *L. brevis* strain of the '730 patent is an arginine using strain too, although the reference is silent. Therefore, this conclusion is not merely conjecture as argued by Applicant.

In addition, likewise citations in the cited prior art supporting an exact passage that cells of oral cavity are similar to ones of vaginal cavity are not necessary when one of ordinary skill in the art would have such information available in the state of the art. One of skill in the art would have known at the time the claimed invention was made that epithelial cells of the oral and vaginal cavities are similar and responsive to similar treatments. Again the examiner reiterates that an effect of potentiating the production of hydrogen peroxide by lactic acid bacteria is intrinsic to the combination of lactic acid bacteria taught by the cited prior art.

Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., use of arginine deiminase lactic acid bacteria to increase production of hydrogen peroxide by hydrogen peroxide-producing lactic acid bacteria) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are only required to provide for an arginine using lactic acid bacteria and Ehret does teach, or at least suggests, such strains.

Also, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Ehret is combined as a secondary teaching with the cited primary '370

patent and any insufficiencies of Ehret are provided in the primary reference because Ehret is only relied upon to show the arginine using property of *L. brevis*. Thus, the arguments are not deemed persuasive for these reasons and those of record, with the exception of the previous argument by the examiner regarding culturing of lactic acid bacteria on an agar-agar plate, although the reference did provide citation "bacteria were placed for culture on an agar-agar plate" at column 7, lines 32-33, after rereading of the reference by the examiner it would appear that Applicant is correct in that more than one plate was used.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deborah K. Ware
November 27, 2004


LEON B. LANKFORD, JR.
PRIMARY EXAMINER



UNITED STATES PATENT AND TRADEMARK OFFICE

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23117	7590	05/19/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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	10/024,199		DE SIMONE, CLAUDIO	
	Examiner		Art Unit	
	Deborah K. Ware		1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
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- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 23-41 are presented for reconsideration on the merits.

Papers

The amendment and change of address filed February 27, 2004, have been received and entered.

Claim Objections

Claim 32 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note that the listing of the components of the Markush group consists of *Lactobacillus casei*, *Lactobacillus crispatus*, *Lactobacillus salivarius*, *Lactobacillus brevis*, *Lactobacillus gasseri*, and *Lactobacillus fermentum*. These are required *Lactobacillus* of claim 23 as well. Therefore, these should be deleted from the Markush group of claim 32.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 38-40 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cavaliere Ved. Vesely et al. (US Patent No. 6,277,370), cited of record.

Claims are drawn to a method of treating infections such as vaginitis by applying to vagina an effective amount of a combination of lactic acid bacteria such as *Lactobacillus brevis* and *Lactobacillus salivarius*.

US Pat '370 teaches the same at the abstract, column 2, lines 24-38, column 3, lines 38-46 and column 4, lines 2 and 3 as well as column 7, lines 30-65 and column 8, lines 9-14.

The claims are identical to the cited disclosure and are therefore, considered to be anticipated by the teachings of the reference.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Ved. Vesely et al. (US Patent No. 6,277,370) in view of Ehret (US Patent No. 6,159,724), both cited of record.

Applicant's arguments filed February 27, 2004, have been fully considered but they are not persuasive. Applicants previously argued in their response of October 29,

2003, that the primary focus of the claimed invention was their alleged discovery that certain lactic acid bacteria potentiate the activity of peroxide-producing lactic acid bacteria and that is the criticality of their claimed invention. Based upon Applicants' assertion a newly presented art rejection was set forth to show the obviousness of modifying potentiating effects of lactic acid bacteria. However, it is believed by the examiners that any potentiating effects would be intrinsic to the combination of lactic acid bacteria. More Lactobacilli being combined in a composition would intrinsically increase the activity of hydrogen peroxide because more of it would be produced. Further, as previously set forth in the advisory of October 23, 2003, Applicants have not shown that the *Lactobacillus brevis* as disclosed by Cavaliere Ved Vesely et al maintained of record does not utilize arginine. Ehret was applied of record to clearly show and teach that *Lactobacillus brevis* does utilize arginine since the Cavaliere Ved Vesely et al maintained of record was silent with respect to this claimed feature. Further, treatment of an oral cavity would have been expected to provide successful results as the cells of the oral cavity are similar to the vaginal cavity. Hydrogen peroxide is applicable to the oral cavity as well as the vaginal cavity and the treatment of inflammation at both sites would have been expected to provide successful results.

The cited Cavaliere Ved Vesely et al reference clearly teach the combination of lactic acid bacteria as claimed by Applicants. Hence, any potentiating activity as provided by the arginine producing lactic acid bacteria and of the combination of lactic acid bacteria is intrinsic to the teachings of the lactic acid bacteria combination. Furthermore, the effectiveness of hydrogen peroxide producing lactic acid bacteria for

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treating inflammation such as vaginitis is clearly taught by Cavaliere Ved. Vesely et al, note the abstract and example 3, column 7, lines 30-45. Note that in Table 3, Lactobacillus salivarius and Lactobacillus gasseri both produce hydrogen peroxide in a culture medium in the presence of Lactobacillus brevis wherein the capability of five species of lactic acid bacteria was examined on an agar-agar plate. It would appear from the teachings of Cavaliere Ved Vesely that all were placed and cultured together on the culture plate. Thus, the potentiating effect of the arginine utilizing lactic acid bacteria upon the hydrogen peroxide producing lactic acid bacteria is intrinsic to the combination of the lactic acid bacteria. Thus, no modification of the cited prior is necessary since the effect is considered to be intrinsic to the combination of lactic acid bacteria applied in the claimed methods.

Furthermore, the Applicant's argument that the cited documents appear to be a picking and choosing is noted, however, the cited documents were particularly selected for their teachings of treating inflammation such as vaginitis using a combination of the bacteria as noted above and as claimed herein. Cavaliere Ved Vesely ('370) newly cited as a sole primary reference once again on the record, is noted above for its teaching of lactic acid bacteria which produce hydrogen peroxide. Thus, a person of skill in the art would select these bacteria as the active ingredients and an increase in hydrogen peroxide production would be intrinsic to the selection of these lactic acid bacteria and not due to any drug which could be added to potentiate activity as disclosed by a previously cited Cavaliere Ved Vesely ('104) document of the last office action. While Ehret clearly teaches Lactobacillus brevis which utilizes arginine, the

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same property is believed to be intrinsic to the *Lactobacillus brevis* as disclosed by Cavaliere Ved. Vesely et al ('370). Therefore, the applied combination of cited prior art is deemed proper and the claims are rendered prima facie obvious over this cited prior art. Also in the absence of convincing and persuasive evidence to the contrary ; or Applicant's failure to provide some reason why *Lactobacillus brevis* of the cited prior art does not utilize arginine or some reason why the lactic acid bacteria combination of the cited prior art would not potentiate hydrogen peroxide activity these two properties are considered to be intrinsic to the teachings of the cited prior art.. Further, hydrogen peroxide is known to be produced by Lactic acid bacteria and hence potentiated thereby as well and to treat vaginitis which is an inflammatory condition using these bacteria is also known.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
May 15, 2004